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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,216	04/01/2004	Andrew Peter Phelan	ISA-008.01	7299
63767	7590	08/09/2006	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, (w/INVERNESS 155 SEAPORT BLVD. BOSTON, MA 02210-2600			GEISEL, KARA E	
			ART UNIT	PAPER NUMBER
			2877	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,216

Applicant(s)

PHELAN ET AL.

Examiner

Kara E. Geisel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,7,9-18 and 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,6,7,9-18,21-30 and 34-40 is/are allowed.
- 6) ☒ Claim(s) 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0506</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on May 25th, 2006 has been entered.

Information Disclosure Statement

The information disclosure statement filed on May 25th, 2006 has been considered by the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-33 are rejected under 35 U.S.C. 101 because merely determining (claim 31, line 12) would not appear to be sufficient to constitute a tangible result, since the outcome of the determining step has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized. See OG Notices: 22 November 2005, "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility".

Part b. *Practical Application the Produces a Useful, Concrete, and Tangible Result* under Section IV *Determine Whether the Claimed Invention Complies with the Subject Matter Eligibility Requirement* of 35 U.S.C. Sec. 101, sentence 3, in the OG Notice from 22 November 2005 states 'In determining

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whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible, and concrete.” Since the last step in claim 31 is not tangible, the entire claim is deemed to not comply with subject matter eligibility requirements. Furthermore, since dependent claims 32-33 do not solve the deficiency of independent claim 31 they are also rejected under 35 U.S.C. 101.

Allowable Subject Matter

Claims 1, 3, 6-7, 9-18, 21-30, and 34-38, are allowed over the prior art of record for the reasons set for in the previous Office Actions (paper numbers 0306 and 031706).

Claims 39-40 are allowed over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

As to claim 39, the prior art of record, taken alone or in combination, fails to disclose or render obvious a device comprising a lateral flow test strip disposed in a test position with respect to a housing, the strip comprising a sample receiving portion extending from the housing and first, second and third zones disposed within the housing, the test strip defining a flow path along which liquid received by the sample receiving portion can sequentially flow to the first, second, and third zones of the test strip, and a processor configured to receive a first and second signal from a first detector and to receive third and fourth signals from a second detector and to determine the presence of an analyte in liquid received by the sample receiving member based at least in part on the first, second, third, and fourth signals, in combination with the rest of the limitations of claim 39.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is 571 272 2416. The examiner can normally be reached on Monday through Friday, 8am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on **571 272 2800 ext. 77**. The fax phone number for the organization where this application or proceeding is assigned is **571 273 8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



F.L. Evans
Primary Examiner
Art Unit 2877



KEG
August 3, 2006